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12/03 5100-1-701 Rev-J



Cleaning, Maintenance & Sterilization Recommendations

IMPORTANT INFORMATION

File in your maintenance records.

This is a comprehensive reference which provides recommendations for cleaning, inspection, lubrication and sterilization of the Total Performance System.

Keep your maintenance records up-to-date!

Check the revision level in the upper right corner. If your file contains an older version, please review this information and update your records.

stryker* INSTRUMENTS

Stryker Instruments 4100 E. Milham Kalamazoo, Michigan (USA) 49001 269-323-7700 1-800-253-3210 European Authorized Rep: RA/QA Manager Stryker France ZAC Satolas Green Pusignan Av. de Satolas Green 69881 MEYZIEU Cedex

European Equivalent 5100-1-713 Rev-C Japanese Equivalent 5100-1-723 Rev-C N. European Equivalent 5100-1-732 Rev-A

Cleaning Recommendations

Instruments must be cleaned and sterilized before first and every use.

IMPORTANT: Before cleaning, disassemble instrument components, including the removal of burs, blades, cords, cutters, handswitches, and attachments from the handpieces.

WARNING: DO NOT use solvents, lubricants, or other chemicals, unless otherwise specified. The use of such materials may cause the instruments to malfunction or leak foreign materials during use which may result in contact with the surgical site.

CAUTION: DO NOT immerse any TPS components or run through a washer/sterilizer.

Console

- Lightly wipe surfaces with a soft cloth dampened with a nonabrasive, standard disinfectant or mild detergent and water. Avoid getting moisture in any openings.
- Clean the display screen with glass cleaner applied to a soft cloth. Never use aerosol sprays directly on the screen.

Footswitch

- 1. Wipe footswitch with mild detergent and rinse with water.
- If electrical connector gets wet, carefully dry with a lint free cloth. If available, forced air drying is preferred.
 NOTE: If immersed, water will seep into footswitch. Drain water through cord bushing while repeatedly depressing pedals to facilitate drainage.

Handpiece Cords Universal Handswitch

- 1. Wipe clean with a mild detergent and water or alcohol.
- 2. Extend finger rest of handswitch to clean all surfaces.
- Rinse with water.
- Dry with a lint-free towel. If available, forced air drying is preferred. Use caution not to bend pins in connectors.

Handpieces

 All Stryker Endoscopy handpieces:
 Refer to the care, maintenance and sterilization instructions supplied with those handpieces.

CAUTION: DO NOT allow water to run into the distal end of the handpiece or into electrical connections.

 Wipe handpiece clean with a lint-free cloth, mild detergent, lvory® soap, or surgical instrument cleaning solution and water. Use a stiff bristle brush to remove debris from the distal end of the handpiece.

■ MicroDriver:

Use a stiff bristle brush to remove debris from the cannula. Wipe surfaces with a water moistened lint-free cloth to wipe away cleaning solution

■ Universal Drill, Quantum Drills and Saws: Hold on an incline, distal tip pointing down, flush with running water to rinse away cleaning solution.

Dry with a lint-free cloth. Pay special attention to electrical connections. If available, forced air drying is preferred.

NOTE: TPS handpieces do not require lubrication.

Attachments (for Micro and Universal Drills) Accessories (for MicroDriver)

CAUTION: Handle Dura Guards with extreme caution. Use care to prevent damage to foot. Ensure debris is cleaned out of the recess inside the foot.

- 1. Clean with a brush or sponge, and mild detergent, such as Ivory® soap, or a surgical instrument cleaning solution.
- Use a stiff bristle brush inside cannula and flush with running water.
- Dry with a lint free towel. If available, forced air drying is preferred.

NOTE: Some instruments require specific instructions, as follows:

■ Right Angle Head Attachment

Reducer and head must remain assembled for cleaning. Follow lubrication instructions specified for Right Angle Head Attachment.

■ MicroDrill Attachments Only Lubricate these

attachments with Stryker ContraClean.™ Follow lubrication instructions specified for MicroDrill Attachments.

■ Cutting Accessories All burs and blades are

All burs and blades are designed for single use only. Reuse significantly increases expensive handpiece wear.

■ All TPS Angled Attachments

DO NOT IMMERSE. Insert a stiff bristle brush into the nose and gently remove debris. Hold on an incline, distal tip pointing down, flush locking ring area with running water to rinse away cleaning solution. Do not allow water to run into either end of the attachment.



Lubrication Instructions (Attachments)

WARNING: DO NOT lubricate TPS handpieces (unless directed otherwise). TPS handpieces are permanently lubricated and should not be lubricated during maintenance. Additional lubrication may cause handpieces to overheat and cause burn injury to the patient and/or user. Additional lubrication may also leak from the handpiece during use and contact the surgical site.

Right Angle Head Attachment

Before each sterilization, lubricate the TPS Right Angle Attachment with **Stryker TPS Lubricant REF 5110-901-900.**

Other lubricants and cleansers leave residue and reduce power transmission.

NOTE: Lubricate with head and reducer assembled.

- Place attachment over the nozzle, push firmly and twist until it snaps into place.
- 2. Tug to ensure it is secure.

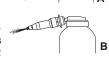


-WARNINGS

Expect substantial pressure from the can when spray button is depressed. If not secure, the pressure will forcefully eject the attachment from the nozzle.

Never release the attachment from the can upon release of button. Attachment must be kept in place until dispersant ceases to flow from the head.

- Hold the can upright and spray for approximately 3 seconds. Spray will disperse from the openings in the head (A).
- Remove head from reducer and flush the reducer with 3 blasts of spray for approx. 2 seconds per blast (B).



- Retract the collar and remove attachment. Wipe away excess lubricant.
- 6. Reassemble reducer and head before sterilization.

Micro Drill Attachments

REF 5100-15-40 REF 5100-15-41 REF 5100-15-42 REF 5100-15-43

Before each sterilization, lubricate the MicroDrill Attachments with Stryker ContraClean™ REF 260-901-739.

Other lubricants and cleansers leave residue and reduce power transmission.

- 1. Place attachment over the nozzle.
- 2. Fasten retaining latch over attachment. Make sure it is



-WARNINGS-

Expect substantial pressure from the can when spray button is depressed. If latch is not secure, the pressure will forcefully eject the attachment from the nozzle.

Do not unfasten latch from attachment upon release of button. Latch must be kept in place until dispersant ceases to flow.

- 3. Hold the can upright and spray for approximately 3 seconds.
- Wipe excess ContraClean from the attachment.
- 5. Remove attachment and sterilize as recommended.

Sterilization Recommendations

IMPORTANT INFORMATION

■ Universal Handswitch REF 5100-9

CAUTION: Remove the Universal Handswitch from the handpiece prior to sterilization. If it remains attached, its band will stretch and no longer fasten to the handpieces.

NOTE: The maximum expected life of the Universal Handswitch is 100 sterilization cycles.

■ Sagittal Attachment REF 5100-10-34



WARNING: When using the TPS method of sterilization, remove the blade mount screw to ensure proper sterilization.

To obtain optimum performance from the instruments and help prevent damage, the following sterilization procedures must be followed.

Handpieces, cords, attachments, and accessories must be sterilized before first and every use.



- WARNINGS -

Separate attachments, cutting accessories and cords from handpieces prior to sterilization.

Use only the sterilization methods recommended below. Other methods can damage handpieces and cause instruments to overheat resulting in injury to patient and/or O.R. staff.

Failure to follow recommended dry times can cause moisture to accumulate inside the handpieces that could result in overheating and may cause burn injury to patient and/or user.

CAUTION: DO NOT sterilize console or footswitch.

NOTE: To ensure comfortable operating temperature, allow handpiece to cool to room temperature after sterilization.

FTO:

- 100% ETO
- 120-135°F (49-57°C)
- Double cloth (muslin) wrapped
- 1 hour minimum exposure time, 8 hour minimum aeration time

250°F Gravity:

- Gravity displacement sterilizer
- 250-254°F (121-123°C)
- Double cloth (muslin) wrapped
- 45 minute minimum exposure time
- 8 minute minimum drying time

Hi Vac:

- Pre-vacuum sterilizer
- 270-272°F (132-134°C)
- Wrapped or unwrapped
- 4 minute minimum exposure time
- 8 minute minimum dry time

270°F Gravity (wrapped):

- Gravity displacement sterilizer
- 270-272°F (132-134°C)
- Single or double cloth wrap in an instrument tray
- 35 minute minimum exposure time
- 8 minute minimum drying time

270°F Gravity (unwrapped):

- Gravity displacement sterilizer
- 270-272°F (132-134°C)
- Unwrapped "Flash"10 minute minimum
- exposure time
- 3-5 minute dry time

Sterilization Recommendations Validation based on AAMI protocol.

Maintenance Recommendations

WARNING: Inspect handpieces to assure proper working order and that there are no loose or missing components. Be aware of unusual sounds or vibrations and note operating speed. Check all moving parts for free movement. DO NOT use instruments if damage is apparent.

CAUTION: DO NOT attempt to service any system component. In the USA, refer calibration, operating difficulties and scheduled maintenance activities to your Stryker Representative or Stryker Customer Service. Outside the USA, contact the nearest Stryker subsidiary.

Periodic Maintenance Schedule

ACTIVITY

INTERVAL

Run handpiece* for 1 minute 3 months to determine temperature. If the distal tip and body of the handpiece become uncomfortably hot to touch (approx. 110°F), return the instrument for service.

*NOTE: The Universal Drill should be checked with each attachment and a bur.

Using a safety analyzer, check 12 months and compare the leakage current, ground impedance and current draw with the limits specified in UL 2601-1 and IEC 60601-1 standards.